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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,297	02/17/2004	Apollon Papadimitriou	20619US1	9601

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HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
340 KINGSLAND STREET
NUTLEY, NJ 07110

EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/780,297

Applicant(s)

PAPADIMITRIOU, APOLLON

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10,12-16,18,22,29-31 and 39-76 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,2,4-10,12-16,18,22,29-31 and 39-76 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 16 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/853,731.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. Claims 1-2, 4-10, 12-16, 18, 22, 29-31 and 39-76 are pending.

Applicants' amendment and a copy of the response to oppositions against EP131128 by patentee filed August 24, 2006 are acknowledged. Applicants' response and the response to oppositions against EP131128 have been fully considered. Claims 1, 4, 12, 13, 22, 29-31, 40, 43, 44, 46, 48, 49, 51 and 53-59 have been amended, claims 3, 11, 23-28 and 32-37 have been cancelled, and new claims 69-76 have been added. Thus, claims 1-2, 4-10, 12-16, 18, 22, 29-31 and 39-76 are examined.

Priority

2. The instant application is a continuation of U.S. Application 09/853,731, filed May 11, 2001, which claims the priority of EP 00110355.5, filed May 15, 2000. The independent claims of instant application have been amended to recite "antioxidant" instead of methionine, which is supported by the priority document of EP 00110355.5 (e.g., page 6) and the instant application (e.g., page 10). Thus, the priority date of independent claims is the filing date of the priority document, May 15, 2000.

Withdrawn Claim Rejections-103(a)

3. The previous rejection of claims 1-5, 9-16, 18, 22-26, 30-39, 46-52 and 59 under 35 U.S.C. 103(a) as being unpatentable over Bailon (U.S. Patent No. 6,583,272) in view of Takuri (U. S. Patent 5,272, 135), is withdrawn in view of applicants' amendment to the claims, applicants' cancellation of the claims, and applicants' response at page 15 of the amendment filed August 24, 2006.

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4. The previous rejection of claims 1-16, 18, 22-39, 46-52 and 59 under 35 U.S.C. 103(a) as being unpatentable over Bailon (U.S. Patent No. 6,583,272) in view of Sato (WO 00/51629), is withdrawn in view of applicants' amendment to the claims, applicants' cancellation of the claims, and applicants' response at page 15 of the amendment filed August 24, 2006.

Withdrawn Claim Rejections-Obviousness Type Double Patenting

5. The previous rejection of claims 3, 11, 23-28 and 32-37 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24, 25, 27-34, 38-42, 51-55, 59-61, 67, 68, 71-77 and 83-108 of copending Application No. 09/853,731 based on allowable claims filed June 26, 2006, is withdrawn in view of cancellation of the claims in the amendment filed August 24, 2006.

New Claim Objection

6. Claim 73 is objected to because of the misspelled word "cystein". Appropriate correction is required.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-2, 4-10, 12-16, 18, 22, 29-31, 39-52 and 59-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 1, 2, 6-10, 12-16, 18, 40-42, 46-52 and 59-76 are indefinite because the claim cites citrate being a multiple charged inorganic anion, in fact citrate is an organic acid. Claims 2, 6-10, 12-16, 18, 40-42, 46-48, 50-52 and 59-76 are included in the rejection because they are

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dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

9. Regarding claim 1, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Claims 2, 4-10, 12-16, 18, 22, 29-31, 39-48, 59-65 and 69-73 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

10. Claim 31 is indefinite because the claim does not further limit claim 30. Claim 22, from which claim 30 depends, already recites the limitation of the concentration of buffer at 10-50 mM.

11. Claim 39 is indefinite because the claim does not further limit claim 22, which recites "wherein the glycoprotein product is a pegylated erythropoietin".

12. Claim 45 is indefinite because the claim recites "10 µg to 10000 µg erythropoietin per ml of solution", while claim 43, from which claims 44 and 45 depend, recites "100 µg to 400 µg erythropoietin per ml of solution", thus claim 45 does not further limit claim 43 in terms of the concentration of erythropoietin.

Maintained Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-2, 4-10, 12-16, 18, 22, 29-31 and 39-76 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24, 25, 27-34, 38-42, 51-55, 59-61, 67, 68, 71-77 and 83-108 of copending Application No. 09/853,731 based on allowable claims filed June 26, 2006. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-2, 4-10, 12-16, 18, 22, 29-31 and 39-76 in the instant application disclose a liquid pharmaceutical composition comprising an amount of a human EPO glycoprotein product sufficient to provide about 10 μg to about 10,000 μg per ml of erythropoietin, about 10 to about 200 mM of a multiple charged inorganic anion of a sulfate, phosphate or citrate, an antioxidant, and a buffer at pH of 5.5 to 7.0, where the EPO product can be a pegylated EPO product. This is an obvious variation in view of claims 24, 25, 27-34, 38-42, 51-55, 59-61, 67, 68, 71-77 and 83-108 in the copending application which disclose a liquid pharmaceutical composition comprising a pegylated EPO glycoprotein product having the in vivo biological activity, a multiple charged inorganic anion and a buffer at pH of 5.5 to 7.0, and the liquid composition is stable at room temperature for at least 6 months; and the specification indicates an antioxidant such as cysteine, methionine, acetylcysteine and ascorbic acid can be added to the composition (paragraph [0044]). Since both the claims of the instant application and the claims of the copending application are directed to a pharmaceutical composition comprising an EPO glycoprotein product such as pegylated EPO product, a multiple charged inorganic anion such as sulfate, a buffer such as phosphate at pH of

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5.5 to 7.0 and an antioxidant such as cysteine, methionine, acetylcysteine and ascorbic acid.

Thus, claims 1-2, 4-10, 12-16, 18, 22, 29-31 and 39-76 in present application and claims 24, 25, 27-34, 38-42, 51-55, 59-61, 67, 68, 71-77 and 83-108 in the copending application are obvious variations of a pharmaceutical composition comprising an EPO glycoprotein product, a multiple charged inorganic anion, an antioxidant, and a buffer at pH of 5.5 to 7.0.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants indicate neither the current application nor the '731 application have allowed claims. Moreover, applicant notes that on September 19, 2005, a terminal disclaimer over the instant application (CD 20619 US1) was already filed in USSN 09/853,731. As such, applicant submits that the request for another terminal disclaimer is improper or at least premature (page 16 of the response).

Applicants' response has been considered, however, the argument is not found persuasive because the claims of '731 application were allowed on September 20, 2006, and the claims of '731 application and the claims of instant application are obvious variations of a pharmaceutical composition comprising an EPO glycoprotein product. A terminal disclaimer is required for instant application to overcome the rejection of obviousness-type double patenting.

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Conclusion

14. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

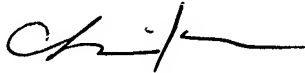
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

November 18, 2006